ATTACHMENT B

REMARKS

By the present amendment, Claim 1 has been amended in a manner so as to completely define the nature of the antigen recognized by the specific antibody of the invention as disclosed throughout the application, e.g., page 7, which shows that the specific M31 subregion, previously identified as amino acids 61-343 of the collagen binding protein, is also described completely as SEQ ID NO: 4. In addition, Claim 2 has been canceled without prejudice, and Claims 6 and 8 have been modified in order to obviate the objection from the Examiner. Since the present amendment overcomes any previous objections and rejections and places the application in condition for allowance, the entrance of the amendment is proper for reasons as stated in more detail below.

In the Official Action, the Examiner rejected the claims under Section 112 on the basis of the Written Description requirement. In short, as was previously shown, the Written Description Guidelines Training Materials as previously submitted show that the disclosure of a fully characterized antigen and an antibody capable of binding to that antigen "meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention." See Guidelines, previously provided, at Example 16, pages 59-60. In this case, the Examiner's rejection is based on the characterization of the antigen as "not well characterized [because] Applicant has merely recited a span of amino acids within an undefined amino acid sequence." See Final Rejection, Page 3. This objection is traversed in that Applicant has defined the precise amino acid structure with a complete sequence, and there is no greater characterization that can be possible. Accordingly, the Examiner's rejection on the basis of the Written Description requirement is traversed and should be withdrawn.

The Examiner also made a rejection on the grounds of enablement, but indeed the arguments regarding enablement appear to only relate to claim 2. Indeed, as indicated in conjunction with the written description requirement, the specification readily enables one skilled in the art to prepare the claimed antibody. See the Written Description guidelines, page 60 wherein the US Patent and Trademark Office correctly recognizes that it is routine in the art to make antibodies to fully characterized antigens. Accordingly, the cancellation of Claim 2 makes the Examiner's rejection on the grounds of enablement moot, and this rejection should now be withdrawn.

Finally, the Examiner's prior art rejection on the basis of the Patti 1995 article seems to be based on a number of incorrect assumptions and statements, and it is clear that any rejection based on this reference, which clearly does not disclose or suggest an antibody that binds SEQ ID NO: 4, should be withdrawn. In particular, the Patti reference discloses the isolation of the M17 subregion and does **not** disclose the isolation of the M31 region (SEQ ID NO: 4) nor any antibodies that bind to that sequence. In maintaining the rejection on the basis of this reference, the Examiner argues that the reference teaches antibodies that are the same as those of the claimed invention. However, this false belief seems to be based on the Examiner's position that "since subregions M!7 and M31 differ by 90 and 44 amino acids at the flanking regions, they would share at least one immunoepitope in the span of 148 amino acids they share" in the absence of evidence to the contrary. In addition, the Examiner states that the presented data show that "the antibody generated to the M17 region (antibody unidentified) bound to the M31 subregion though with less efficiency." See Final Rejection, pages 12-13. Again, such arguments are incorrect and show that the Examiner has not properly considered the information in the Declaration.

In the first place, the Examiner's comment that "the antibody generated to the M17 region (antibody unidentified) bound to the M31 subregion though with less efficiency" cannot be correct because the information provided in the Declaration (copy attached) related to antibodies generated against the M55 region and **not** the M17 region. See Declaration, ¶4. Moreover, to the extent there is any information provided about the recognition of the M17 region, the information shows that **none** of the antibodies to M55 recognized the M17 at all. Id. Accordingly, since there is overlap between M17 (151-297) and the M55 region (30-529), based on the Examiner's argument that these regions "would share at least one immunoepitope" one would expect that antibodies to M55 would recognize M17. However, the Declaration shows to the contrary that the antibodies to M55 did **not** recognize M17, and thus the evidence presented completely contradicted the Examiner's point that there would inherently be such recognition.[1]

In short, the only relevant part of the one cited Patti reference is the disclosure of M17 and antibodies thereto. However, the previously filed Declaration shows that the 1995 Patti article does not disclose or suggest the M31 region at all, much less antibodies thereto, and the evidence provided in the Declaration completely contradicts the Examiner's position that such antibodies would inherently be included in the disclosure when in fact Applicant has provided evidence that antibodies to a larger region, M55 (30-529) in fact did **not** recognize the region M17. In other words, it is clear

[1] The Examiner's assertion that the M55 region as referred to in he Declaration was smaller that M31 because it was to the region "50-329" is clearly incorrect since the Examiner recognized that the specification accurately describes the M55 region as from 30-529. The reference in the Declaration to "50-329" was clearly an inadvertent error, and it is clear that it was intended to reflect the sequence of M55 as 30-529 as the Examiner should have recognized.

that the cited Patti et al. reference does not disclose or suggest the claimed antibodies to M31, SEQ ID NO:4, and indeed the evidence provided by Applicants shows conclusively that those antibodies are somehow inherent in that disclosure. Accordingly, upon entrance of the present amendment, the Examiner's rejection of the claims on the basis of the 1995 Patti et al. reference, insofar as applied to the claims as amended, is respectfully traversed and should be withdrawn.

One remaining objection was the Examiner's question with regard to the "isolated" antisera. Applicants have now amended these claims so that they relate to "Antisera", and this term is well defined in the art and would immediately be recognized and understood by one skilled in the art.

In light of the amendments and arguments as set forth above, and the attachments hereto, Applicants respectfully submit that upon entrance of the present amendment, the present claims will be placed in condition for allowance, and such action is respectfully requested.

END OF REMARKS